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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,578	10/26/2001	Jeffrey S. Kiel	KIEL / 02	4696

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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	5

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,578	KIEL ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *22-31 and 49-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,31-48 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election of Restriction Requirement Acknowledged.

1. Applicants election with traverse the Group I, claims 1-21 and 53, is acknowledged. Applicants traverse the restriction requirement on the grounds that there would be no burden in searching the entire groups. This argument is not persuasive, as claimed invention would be distinctive, each from the other for the reason of the record. Furthermore, the search of the entire groups in the non-patent literature (a significant part of a through examination) would be burdensome. Therefore, the requirement is still deemed proper, and made Final.

In response to applicant's inadvertent error of failing to further limit previous subject matter of the claim 32-48, applicant's argument is deemed persuasive. Therefore, claims 32-48 will be included in Group I invention. However, Claims 22-31 and 49-52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims, the requirement having been traversed in Paper No. 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-21, 31-48 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 31 and 53 recite the step of dissolving the active ingredients such as phenylephrine and pyrilamine in a "first solvent". However, it is not clear what "first solvent" refers to. The specification fails to define clearly what agents could be used as the "first solvent".

Does it refer to water? Or other solvents (e.g., ethanol, diethylether, methylene chloride, acetone and isopropyl alcohol)? Furthermore, it is not clear at all how "first solvent" differs from "second solvent". Applicants are requested to clarify.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-21, 31-48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordiziel (US 6287597) in view of Chopdekar et al. (US 5599846).

Gordiziel discloses a composition, comprising phenylephrine tannate and chlorpheniramine tannate, benzoic acid, coloring, natural and artificial flavors, glycerin, kaolin, magnesium aluminum silicate, methyl paraben, pectin, purified water, saccharin, sodium hydroxide and sucrose or sorbitol, wherein said composition is prepared in a conventional manner (column 2, lines 51-64 and Example 2). Gordiziel discloses that beside the conventional isopropanol route, antihistamines in the form of their tannate salts can be prepared alternatively in the water route (column 1, line 60 thru column 2, line 6).

Chopdekar discloses an antihistamine tannates (e.g., phenylephrine, pyrilamine, etc...) prepared by water route. Chopdekar teaches or suggests the advantage of preparing antihistamine tannates in water route compared to the conventional isopropanol route, wherein the water route yields about 90-97% of the tannate salts proudcts and about 90-98% of the product purity compared to only about 70% of the yields and about 85-90% wt % of the purity in the isopropanol route.

As indicated in preceding statement, both the referenced composition (Gordiziel) and the claimed composition (final composition prepared by the claimed steps) are directed to the same composition. However, the teaching of Gordiziel'597 differs from the claimed invention in (i) the specific step of making said composition by the water route, namely step of conversion of the active pharmaceutical ingredients into tannate salts prepared by reacting phenylephrine and

pyrilamine in the form of free base with tannic acid in the presence of water and mixing with the known secondary agents to derive at the claimed composition; (ii) the specific amounts (or ratios) of active and/or inactive ingredients in a composition; and (iii) the specific pH of the said composition. To incorporate such teaching into the teaching of Gordiziel, would have been obvious in view of Chopdekar who teaches or suggests the advantage of preparing antihistamine tannate in water route.

One having ordinary skill in the art would have been motivated to prepare the claimed composition by the water route such that the yield and the purity of antihistamine (pyrilamine and phenylephirne) tannates would be greatly increased. Although the prior art references in combination do not specifically disclose the claimed order (or step) of preparing said composition, such determination of order of performing step is prima facie obvious in the absence of new or unexpected results.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

In addition, optimization of amounts (or ratios) of known active and inactive ingredients in a composition or determination of optimum pH is well considered within the skill of the artisan, absent evidence to the contrary.

Conclusion

4. No Claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Zohreh Fay